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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/677,734

10/01/2003

Kevin H. Gardner

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4912

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12/14/2005

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/677,734

Applicant(s)

GARDNER ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's response, on October 13, 2005 to the First Action on the Merits of this case mailed July 14, 2005, is acknowledged. It is acknowledged that applicants have cancelled Claims 2-20 and amended Claim 1. Claim 1 is pending and is hereby considered.

#### ***Specification-Objections***

Applicants responded, with an appropriate amendment, to the prior objection to the specification, wherein an article is missing on page 4, lines 18-20. However, it is noted that Applicants have stated that the amendment is on page 3, rather than page 4.

Objection to the specification because it states that Rutter et al, 2001 teaches that PAS kinase regulates sugar metabolism (pg 15, lines 25-26), but Rutter et al, 2001 do not disclose said teachings, is maintained.

Objection to the specification because the phrase "inform the mode of kinase regulation by the PAS domain", on page 16, lines 1-2, is not proper English, is maintained. Applicants neither amended the specification nor commented on said objection.

Applicants' amendment to the specification, citing Rutter et al, 2002 (pg 15, line 26 & pg 24, line 30) is objected to for introducing New Matter because Rutter et al, 2002 was not disclosed in the specification or claims, as filed.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

***Double Patenting***

Rejection of Claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 11 of US Patent 6,319,679, for the reasons set forth in the prior action, is maintained. Applicants did not comment on this rejection. It is noted that, amendment of Claim 1 herein to specifically recite the PAS domain set forth by AF387103 does not overcome the instant rejection because said PAS domain is identical to the PAS domain taught by US 6,319,679. Moreover, the full-length protein set forth by AF387103 is identical to SEQ ID NO: 2 of US 6,319,679 (see enclosed alignment), which is disclosed in US 6,319,679 (col 15, line 61- col 16, line 67) as being used in the method recited in Claim 1 herein.

***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons. Recitation of a Genbank accession number, AF387103, in Claim 1 renders the claim indefinite, as the content contained at the Web site disclosing the sequence identified by said Accession number may change over time. The phrase “wherein the PAS domain is PAS kinase PAS A” is confusing and indefinite for two reasons. First, it is unclear whether said phrase is meant to recite wherein the PAS domain is PAS A domain of PAS kinase or something else. Second, if Applicants’ intention is to define the structure of the PAS A domain by reference to Genbank accession number AF387103, said phrase is also indefinite for the reasons provided in the prior paragraph. Therefore, Claim 1 is rejected under 35 U.S.C. 112,

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second paragraph, as being indefinite. A person of ordinary skill in the art would not know the metes and bounds of the recited invention.

***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Enablement**

Rejection of Claim 1 under 35 U.S.C. 112, first paragraph, for lack of enablement, for reasons described in the prior action, is maintained. Applicants did not comment on this rejection. It is noted that Claim 1, as amended, recites a method using the PAS domain set forth by Genbank Accession No. AF387103, wherein binding specificity of said domain is manifested as a change in kinase activity. The claim fails to provide any structural limitation for the kinase linked to said PAS domain and, thus, said claim encompasses a method using any protein with any structure, wherein the protein comprises the PAS domain of AF387103 and has any kinase activity. The specification fails to enable the skilled artisan to make any protein with any structure, wherein the protein comprises the PAS domain of AF387103 and has any kinase activity; moreover, the specification fails to enable the skilled artisan to use any said protein in a method of changing a functional surface binding specificity of the PAS domain, wherein the change in binding is manifested as a change in any kind of kinase activity, measured by any steps and reagents. Furthermore, as stated in the prior action, the specification does not support the broad scope of Claim 1 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting the function of any kinase having a PAS

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domain or the activity of any PAS kinase; (B) the general tolerance of the kinase activity of any said proteins to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices of proteins is likely to be successful in the recited methods; and (H) the specification provides insufficient guidance as to which of the essentially infinite possible choices of steps and reagents is likely to be successful in the recited methods. For these reasons and those further explained in the prior action, rejection of Claim 1 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained.

#### **Written Description**

Rejection of Claim 1 under 35 U.S.C. 112, first paragraph, for the reasons explained in the prior action, is maintained. Applicants did not comment on this rejection. It is noted that Claim 1, as amended, recites a genus of methods using a genus of proteins with any structure wherein the protein comprises the PAS domain of Genbank Accession No. AF387103 and the protein has any kinase activity. Said genus of methods encompass any method of changing a functional surface binding specificity of the PAS domain of said any protein, wherein the change in binding is manifested as a change in kinase activity. As stated in the prior action, the specification teaches the structure of only a single representative species of such PAS domain-containing kinases and teaches no such methods, while the prior art teaches only a single representative species of said methods (McKnight et al, 2001). Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to

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sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claim 1 under 35 U.S.C. 102(b), as being anticipated by McKnight et al, 2001, for the reasons described in the prior action, is maintained. Applicants did not comment on this rejection. It is noted that, amendment of Claim 1 to specifically recite the PAS domain set forth by AF387103 does not overcome the instant rejection because said PAS domain is identical to the PAS domain taught by McKnight et al. Moreover, the full-length protein set forth by AF387103 is identical to SEQ ID NO: 2 of McKnight et al (see enclosed alignment), which is used by McKnight et al (col 15, line 61- col 16, line 67) in the method recited in Claim 1 herein. Therefore, rejection of Claim 1 under 35 U.S.C. 102(b), as being anticipated by McKnight et al, 2001, is maintained.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claim 1 under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Amezcua et al, 2002, for the reasons described in the prior action, is maintained. Applicants did not comment on this rejection. It is noted that, amendment of Claim 1 to specifically recite the PAS domain set forth by AF387103 does not overcome the instant rejection because said PAS domain is identical to the PAS domain used by Amezcua et al and the full-length protein set forth by AF387103 is identical to the full-length protein used by Amezcua et al (pg 1349, para 3, ref [7]). Therefore, rejection of Claim 1 under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Amezcua et al, 2002, is maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claim 1 under 35 U.S.C. 103(a) as being unpatentable over Fejzo et al, 1999 in view of Rutter et al, 2001 and further in view of Rutter et al, 2002 or Katschinski et al, 2003, for the reasons described in the prior action, is maintained. Applicants did not comment on this



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rejection. It is noted that, amendment of Claim 1 herein to specifically recite the PAS domain set forth by AF387103 does not overcome the instant rejection because said PAS domain is the PAS domain taught by Rutter et al, 2001 and the full-length protein set forth by AF387103 is the full-length protein taught by Rutter et al, 2001 (Genbank AF387103). Therefore, rejection of Claim 1 under 35 U.S.C. 103(a), as being unpatentable over Fejzo et al, 1999 in view of Rutter et al, 2001 and further in view of Rutter et al, 2002 or Katschinski et al, 2003, is maintained.

Applicant's amendment necessitated any new grounds of rejection or objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.

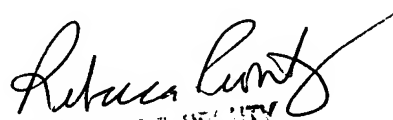
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.

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